REMARKS

Claims 1-10, 12, 17-31, 36-48, 50, 55-57, 59, 61-62, 73-82 and 93-153 are pending in this application. Claims 1, 17-20, 36-39, 59, 61, 62, 73-74 and 100-102 have been amended. Claims 11, 13-16, 32-35, 49, 51-54, 58, 60, 63-72 and 83-92 have been canceled. Claims 111-153 have been added. Support for the amendments and new claims is found in the specification and claims as filed.

Claim Rejection - 35 U.S.C. § 103(a)

Claims 1-10, 12, 14, 17-31, 33, 36-48, 50, 52, 55-57, 59, 61-67, 73-82 and 93-110 have been rejected under 35 U.S.C. §103(a) as obvious over U.S. Publication No. 2002/0161288 to Shin et al. ("Shin") in view of the "The MiniMed Continuous Glucose Monitoring System," Diabetes Technology & Therapeutics, Volume 2, Supplement 1, 2000, Mary Ann Liebert, Inc., pp. S-13 to S-18 ("Mastrototaro") and U.S. Patent No. 6,558,320 to Causey III ("Causey"). The rejected claims each depend from one of Claims 1, 20, 39, 59, 61 and 62. To establish a *prima facie* case of obviousness, three basic criteria must be met: first, the prior art reference (or references when combined) must teach or suggest all the claim limitations; second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; finally, there must be a reasonable expectation of success. *See* M.P.E.P. § 2143.

Claim 1 recites a method for evaluating a quality of calibration in an analyte sensor including, *inter alia,* evaluating a quality of said calibration set using a statistical and/or clinical association of at least one matched data pair and controlling a user interface responsive to the quality of said calibration set.

Claim 20 recites a system for evaluating a quality of a calibration of an analyte sensor, including, *inter alia,* means for evaluating a quality of said calibration set using a statistical and/or clinical association of at least one matched data pair; and means for controlling a user interface responsive to the quality of said calibration set.

Claim 39 recites a computer system for evaluating a quality of a calibration of an analyte sensor, including, *inter alia,* a quality evaluation module that evaluates a quality of said calibration set using a statistical and/or clinical association of at least one matched data pair; a

sensor data transformation module that converts sensor data into calibrated data using said calibration set; and an interface control module that controls a display of a user interface responsive to the quality of said calibration set.

Claim 59 recites a method for evaluating a quality of a calibration of an analyte sensor, including, *inter alia*, evaluating a quality of said at least one matched data pair based on a statistical and/or clinical association of reference analyte data and substantially time corresponding sensor data; and converting the sensor data into calibrated data responsive to the quality of the at least one matched data pair meeting a criterion.

Claim 61 recites a computer system for evaluating a quality of a calibration of an analyte sensor, including, *inter alia*, a quality evaluation module configured to evaluate a quality of said at least one matched data pair based on a statistical and/or clinical association of reference data and substantially time corresponding sensor data for said at least one matched data pair, wherein the processor module is configured to convert the sensor data into calibrated sensor data responsive to the quality of the at least one matched data pair meeting a criterion.

Claim 62 recites a method for evaluating a quality of a calibration of a glucose sensor, including, *inter alia*, evaluating a quality of said calibration set based on a statistical analysis and/or a clinical acceptability analysis of at least one matched data pair; and processing real-time sensor data responsive to the quality of said calibration set meeting a criterion.

Shin discloses a method of calibrating a glucose sensor, however does not evaluate the quality of the calibration set, as addressed by the Examiner in the previous office action. Mastrototaro teaches evaluation of accuracy of a retrospective data set. Causey teaches that calibration may be performed on a real-time basis and/or backwards recalibrated (e.g., retrospectively). Examiner asserted, in the previous office action, that in view of Causey, it would have been obvious to modify the Shin/Mastrototaro combination to calibrate in real time, as it is merely the substitution of one equivalent calibration technique for another. However, modifying a retrospective accuracy evaluation performed on a historical data set into a real time quality evaluation of matched data pairs used for real time calibration would not have been merely a substitution of one equivalent calibration technique for another. As discussed in the Declaration of Apurv Kamath attached hereto, because a prospective (real-time) implementation of a conventionally statistical and/or clinical data analysis method cannot take into account what

will happen in the future, additional considerations must be included in the implementation of the prospective algorithm, which are beyond routine experimentation, to ensure that the statistical and/or clinical data analysis that takes into account only information available *prior to* the data point being analyzed, will be adequately predictive such that it is useful in data processing (e.g., sensor calibration) for data going *forward in time*. Accordingly, Applicants respectfully request withdrawn of the current rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
09/916386	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	7/27/2001
10/768889	MEMBRANE FOR USE WITH IMPLANTABLE DEVICES	1/29/2004
11/021162	SENSOR HEAD FOR USE WITH IMPLANTABLE DEVICES	12/22/2004
08/811473	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	3/4/1997

09/447227	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	11/22/1999
11/021046	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	12/22/2004
10/153356	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	5/22/2002
11/404418	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
11/280672	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
11/280102	TECHNIQUES TO IMPROVE POLYURETHANE MEMBRANES FOR IMPLANTABLE GLUCOSE SENSORS	11/16/2005
10/646333	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	8/22/2003
11/416058	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
11/416346	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
11/415631	OPTIMIZED SENSOR GEOMETRY FOR AN IMPLANTABLE GLUCOSE SENSOR	5/2/2006
10/647065	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	8/22/2003
10/842716	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/10/2004
11/416825	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
11/416734	BIOINTERFACE MEMBRANES INCORPORATING BIOACTIVE AGENTS	5/3/2006
11/654135	POROUS MEMBRANES FOR USE WITH IMPLANTABLE DEVICES	1/17/2007
10/633367	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
10/896637	ROLLED ELECTRODE ARRAY AND ITS METHOD FOR MANUFACTURE	7/21/2004
10/896639	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	7/21/2004
11/410392	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006
11/675063	ANALYTE SENSOR	2/14/2007
11/410555	OXYGEN ENHANCING MEMBRANE SYSTEMS FOR IMPLANTABLE DEVICES	4/25/2006

10/897377	ELECTROCHEMICAL SENSORS INCLUDING ELECTRODE SYSTEMS WITH INCREASED OXYGEN GENERATION	7/21/2004
10/897312	ELECTRODE SYSTEMS FOR ELECTROCHEMICAL SENSORS	7/21/2004
10/632537	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
11/038340	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	1/18/2005
10/633404	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
11/865660	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	10/1/2007
10/633329	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	8/1/2003
10/648849	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/22/2003
11/498410	SYSTEMS AND METHODS FOR REPLACING SIGNAL ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	8/2/2006
11/763215	SILICONE COMPOSITION FOR BIOCOMPATIBLE MEMBRANE	6/14/2007
11/007920	SIGNAL PROCESSING FOR CONTINUOUS ANALYTE SENSOR	12/8/2004
10/991353	AFFINITY DOMAIN FOR ANALYTE SENSOR	11/16/2004
11/007635	SYSTEMS AND METHODS FOR IMPROVING ELECTROCHEMICAL ANALYTE SENSORS	12/7/2004
10/991966	INTEGRATED RECEIVER FOR CONTINUOUS ANALYTE SENSOR	11/17/2004
11/055779	BIOINTERFACE WITH MACRO-AND MICRO-ARCHITECTURE	2/9/2005
10/789359	INTEGRATED DELIVERY DEVICE FOR CONTINUOUS GLUCOSE SENSOR	2/26/2004
11/004561	CALIBRATION TECHNIQUES FOR A CONTINUOUS ANALYTE SENSOR	12/3/2004
11/543707	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/543539	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/543683	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006
11/543734	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/4/2006

11/034344	IMPLANTABLE DEVICE WITH IMPROVED RADIO FREQUENCY CAPABILITIES	1/11/2005
11/034343	COMPOSITE MATERIAL FOR IMPLANTABLE DEVICE	1/11/2005
10/838912	IMPLANTABLE ANALYTE SENSOR	5/3/2004
10/838909	IMPLANTABLE ANALYTE SENSOR	5/3/2004
10/838658	IMPLANTABLE ANALYTE SENSOR	5/3/2004
10/885476	SYSTEMS AND METHODS FOR MANUFACTURE OF AN ANALYTE-MEASURING DEVICE INCLUDING A MEMBRANE SYSTEM	7/6/2004
11/077759	TRANSCUTANEOUS MEDICAL DEVICE WITH VARIABLE STIFFNESS	3/10/2005
11/077715	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077883	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077739	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077740	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077765	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/078230	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/078232	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077713	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077693	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077714	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/077763	METHOD AND SYSTEMS FOR INSERTING A TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/925603	TRANSCUTANEOUS ANALYTE SENSOR	10/26/2007
11/077643	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/078072	TRANSCUTANEOUS ANALYTE SENSOR	3/10/2005
11/360262	ANALYTE SENSOR	2/22/2006
11/411656	ANALYTE SENSOR	4/26/2006
11/360299	ANALYTE SENSOR	2/22/2006
11/439630	ANALYTE SENSOR	5/23/2006
11/373628	SYSTEM AND METHODS FOR PROCESSING ANALYTE SENSOR DATA FOR SENSOR CALIBRATION	3/9/2006
11/404929	ANALYTE SENSING BIOINTERFACE	4/14/2006
11/335879	CELLULOSIC-BASED INTERFERENCE DOMAIN FOR AN ANALYTE SENSOR	1/18/2006

11/654140	MEMBRANES FOR AN ANALYTE SENSOR	1/17/2007
11/413238	CELLULOSIC-BASED RESISTANCE DOMAIN FOR AN ANALYTE SENSOR	4/28/2006
11/157746	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
11/157365	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
11/158227	TRANSCUTANEOUS ANALYTE SENSOR	6/21/2005
11/334876	TRANSCUTANEOUS ANALYTE SENSOR	1/18/2006
11/360252	ANALYTE SENSOR	2/22/2006
11/360819	ANALYTE SENSOR	2/22/2006
11/333837	LOW OXYGEN IN VIVO ANALYTE SENSOR	1/17/2006
11/404417	SILICONE BASED MEMBRANES FOR USE IN IMPLANTABLE GLUCOSE SENSORS	4/14/2006
11/360250	ANALYTE SENSOR	2/22/2006
11/842151	ANALYTE SENSOR	8/21/2007
11/543396	ANALYTE SENSOR	10/4/2006
11/543490	ANALYTE SENSOR	10/4/2006
11/543404	ANALYTE SENSOR	10/4/2006
11/691426	ANALYTE SENSOR	3/26/2007
11/691432	ANALYTE SENSOR	3/26/2007
11/691424	ANALYTE SENSOR	3/26/2007
11/691466	ANALYTE SENSOR	3/26/2007
11/750907	ANALYTE SENSORS HAVING A SIGNAL-TO-NOISE RATIO SUBSTANTIALLY UNAFFECTED BY NON-CONSTANT NOISE	5/18/2007
11/855101	TRANSCUTANEOUS ANALYTE SENSOR	9/13/2007
11/515443	SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA	9/1/2006
11/762638	SYSTEMS AND METHODS FOR REPLACING SIGNAL DATA ARTIFACTS IN A GLUCOSE SENSOR DATA STREAM	6/13/2007
11/692154	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	3/27/2007
11/865572	DUAL ELECTRODE SYSTEM FOR A CONTINUOUS ANALYTE SENSOR	10/1/2007
11/681145	ANALYTE SENSOR	3/1/2007
11/503367	ANALYTE SENSOR	8/10/2006
11/690752	TRANSCUTANEOUS ANALYTE SENSOR	3/23/2007
11/734184	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007

11/734203	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
11/734178	TRANSCUTANEOUS ANALYTE SENSOR	4/11/2007
11/445792	ANALYTE SENSOR	6/1/2006
11/546157	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	10/10/2006
10/846150	ANALYTE MEASURING DEVICE	5/14/2004
09/489588	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/21/2000
10/657843	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	9/9/2003
09/636369	SYSTEMS AND METHODS FOR REMOTE MONITORING AND MODULATION OF MEDICAL DEVICES	8/11/2000
09/916858	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	7/27/2001
11/039269	DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS	1/19/2005
07/216683	BIOLOGICAL FLUID MEASURING DEVICE	7/7/1988

Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns that might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 2/25/08

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